No. 17-8151

IN THE

Supreme Court of the United States

RUSSELL BUCKLEW,
Petitioner,

v.

ANNE L. PRECYTHE, DIRECTOR, DEPARTMENT OF CORRECTIONS, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

BRIEF OF *AMICI CURIAE* PHARMACY, MEDICINE, AND HEALTH POLICY EXPERTS IN SUPPORT OF PETITIONER

JESSICA L. ELLSWORTH*
Counsel of Record
PHILIP KATZ
LYNN W. MEHLER
LOWELL M. ZETA
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5886
jessica.ellsworth@hoganlovells.com
Counsel for Amici Curiae

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BRIEF OF *AMICI CURIAE* PHARMACY, MEDICINE, AND HEALTH POLICY EXPERTS IN SUPPORT OF PETITIONER

STATEMENT OF INTEREST[1]

Amici curiae are individuals with extensive experience as medical professionals, scientists, lawyers, and public servants. They have spent careers seeking to protect the public health and ensure the safety

[1] No party or counsel for a party authored this brief in whole or in part. No party, counsel for a party, or person other than *amici curiae*, their members, or counsel made any monetary contribution intended to fund the preparation or submission of this brief. Petitioner and Respondents filed blanket *amicus* consent letters.

and efficacy of pharmaceuticals in the United States. *Amici* and their current positions are listed in the Appendix to this brief.

Amici are participating because they are gravely concerned about the escalating public health risks that States have created by continuing to rely on lethal injection as their primary method of execution, even when they cannot lawfully obtain the drugs necessary to conduct a lethal injection in adherence with established protocols. The stakes could not be higher: States are willingly undermining the federal drug control regime; they are seeking execution drugs through unauthorized channels and importing unapproved products or ingredients from overseas suppliers who are not subject to U.S. inspection or oversight; they are relying on pharmacy compounding to produce a finished product even though compounding pharmacies are virtually unregulated in that regard; and they are actively violating the rules laid out in federal law for registration, importation, distribution, and security controls to prevent abuse and diversion. Each of these facts is problematic individually from a public health perspective. Collectively, they could lead to a public health crisis.

It is of the utmost importance that the Court clarify that its holding in *Glossip* v. *Gross*, 576 U.S. ___, 135 S. Ct. 2726 (2015), does not authorize States to violate federal and state laws in their efforts to conduct lethal injections. The federal and state laws at play are essential to protecting public health by ensuring the safety and efficacy of drugs, and an opinion that sanctions States' willful noncompliance with or secret avoidance of these laws will further

exacerbate the risks to patients and the broader public.[2]

SUMMARY OF ARGUMENT

There can be no real debate that lethal injection as it exists today poses numerous difficulties as a matter of law and medicine. One major consequence of these difficulties is that States have created serious public health risks in their efforts to conduct lethal injections. Unable to obtain the drugs for established protocols through lawful means, States have resorted instead to violating laws and regulations essential to ensuring the safety and effectiveness of pharmaceutical products and to protecting the public health. And they have enacted secrecy laws that authorize them to mask additional potentially unlawful activities and keep the public from knowing—or holding them accountable for—their actions.

The two primary federal laws at issue—the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, and the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*—broadly protect public health in this country. They prevent unsafe, ineffective, improperly labeled, sub-standard, contaminated, adulterated, misbranded, and counterfeit drugs from entering or being distributed in the United States, and they make unlawful the diversion and misuse of particularly dangerous and addictive drug products.

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[2] *Amici* take no position with respect to capital punishment in the United States. Nor do they take a position on the alternative method of execution that Petitioner proposes.

As States have changed their execution protocols to expand the drugs and combinations of drugs that may be used for lethal injection, a number of the new entrants to execution protocols are dangerous drugs of abuse that are controlled under the CSA. These drugs include Fentanyl, Pentobarbital, and Hydromorphone, all Schedule II controlled substances.

As a result of the FDCA and the CSA, the pharmaceutical supply chain is carefully regulated from ingredients to finished product. But States have circumvented this carefully and extensively regulated supply chain to acquire drugs for use in lethal injection. They use overseas sellers, unlicensed middlemen, and secret compounding pharmacies. The result is twofold: it undermines federal laws that protect the public health, and it circumvents pharmaceutical companies' ability to ensure the safety and effectiveness of drugs in the supply chain.

In addition, an increasing number of States have enacted secrecy laws for the purpose of shielding from public and regulatory view how they acquire, prepare, and use illegal—and illegally obtained—drugs in lethal injections. These laws may facilitate execution by lethal injection, but they do so at an extremely high cost: they undermine key federal laws protecting the integrity of the pharmaceutical supply chain and public health.

The risks of all of this behavior by States in their pursuit of drugs to use for lethal injections are not merely theoretical. Drugs obtained by States ostensibly for lethal injection have been diverted from that

use and have reached the patient population.[3] Similarly, patients have been exposed to substandard drugs compounded at pharmacies operating under the cover of "execution secrecy" laws that effectively place the compounders beyond the scope of regulation by federal and state authorities.

This behavior by States puts patients and the public at risk. It cannot be condoned by this Court. Respondents' proposed reading of *Glossip* would have the practical impact of endorsing lethal injection as the only available method of carrying out capital punishment and would exacerbate these risks. It would also increase the likelihood of substandard drugs making their way into the stream of commerce via illicit and hidden pathways, and it would undermine the carefully regulated system of drug distribution that exists to protect public health. This case presents the Court an opportunity to make clear that States may not evade compliance with laws intended to safeguard public health in the pursuit of lethal injections.

ARGUMENT

When the original lethal injection protocol came into existence in 1977, it consisted of three drugs—Sodium Thiopental (an anesthetic), Pancuronium Bromide (a paralytic agent), and Potassium Chloride (which causes cardiac arrest)—that were all readily

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[3] *See Beaty* v. *FDA*, 853 F. Supp. 2d 30, 42 & n.8 (D.D.C. 2012), *aff'd in part, vacated in part sub nom. Cook* v. *FDA*, 733 F.3d 1 (D.C. Cir. 2013).

available for ordinary medical use.[4] Over time, however, that changed. By 2011, another drug—Propofol—had almost entirely replaced Sodium Thiopental in clinical settings.[5] States, in response, began adding new drugs to their execution protocols. The Companies who the U.S. Food and Drug Administration (FDA) had approved to manufacture and distribute the newly added drugs began including provisions in their sales contracts that would prevent the drugs from being used in executions.[6]

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[4] *State by State Lethal Injection*, DEATH PENALTY INFO. CTR., https://deathpenaltyinfo.org/state-lethal-injection (last visited July 23, 2018).

[5] Sodium Thiopental, which was first used in humans in 1934, was replaced by Propofol on the World Health Organization's List of Essential Medicines in 2011. *See* World Health Org., WHO Model List of Essential Medicines 1 (17th ed. March 2011), *available at* http://apps.who.int/iris/bitstream/handle/10665/70640/a95053_eng.pdf?sequence=1. Abbott Laboratories stopped marketing its sodium thiopental product in 2001 and withdrew its New Drug Application (NDA). *See* Letter from Steven Porter, Dir., Los Angeles Dist. Office, FDA 5 n.5 (Apr. 20, 2017), *available at* https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM555224.pdf. In 2011, the sole remaining manufacturer of sodium thiopental also discontinued its production and distribution of the drug. Press Release, Hospira, Hospira Statement Regarding Pentothal (Sodium Thiopental) Market Exit (Jan. 21, 2011), *available at* https://www.evaluategroup.com/Universal/View.aspx?type=Story&id=235611.

[6] Erik Eckholm, *Pfizer Blocks the Use of Its Drugs in Executions*, N.Y. TIMES (May 13, 2016), https://www.nytimes.com/2016/05/14/us/pfizer-execution-drugs-lethal-injection.html; Eric Palmer, *Johnson & Johnson Objects to a Janssen-Developed Drug's Use in Executions*, FIERCEPHARMA (Aug. 22, 2017, 8:55

Some States reacted to that by looking to alternative sources of these drugs with little regard for the legality of the transaction or the quality of the drug product.[7] Certain States thus moved to a world in which they treat the pursuit of lethal execution as sanctioning violations of federal laws that protect the health of U.S. patients by safeguarding the safety and effectiveness of drug products in the United States.

States' continued reliance on lethal injection as their primary method of execution when they cannot lawfully obtain the drugs necessary for established protocols has created serious public health risks. Many States are undermining the drug control regime, seeking execution drugs through unauthorized channels, importing unapproved products or ingredients from overseas suppliers not subject to U.S. inspection or oversight, obtaining finished products from compounding pharmacies not regulated in that regard, and are acting outside the bounds of federal law restrictions on registrations, importation, distribution, and security controls to prevent abuse and diversion. It is critical from a public health perspective that the Court make clear that States may not—in their pursuit of lethal injection—

AM), https://www.fiercepharma.com/pharma/j-j-objects-to-a-drug-developed-by-janssen-for-use-execution.

[7] Lincoln Caplan, *The End of the Open Market for Lethal Injection Drugs*, THE NEW YORKER (May 21, 2016), https://www.newyorker.com/news/news-desk/the-end-of-the-open-market-for-lethal-injection-drugs; John Schwartz, *Seeking Execution Drug, States Cut Legal Corners*, N.Y. TIMES (Apr. 13, 2011), https://www.nytimes.com/2011/04/14/us/14lethal.html.

operate outside of the carefully constructed federal regulatory system that governs the manufacturing and distribution of pharmaceutical products, including controlled substances.

I. FEDERAL LAW PROTECTS THE INTEGRITY OF THE U.S. DRUG SUPPLY CHAIN.

By design, federal law creates a "closed system" of drug distribution. This pervasively and strictly controlled system is intended to ensure that drugs distributed in the U.S. are safe and effective by safeguarding the integrity of the drug supply chain and mitigating the risk of dangerous drugs being diverted and misused.

The FDCA and its implementing regulations establish mandatory requirements for drug approval and labeling, manufacturing quality, and supply chain security. Congress assigned primary responsibility for administering and enforcing the FDCA to the FDA.[8] Among other things, the FDA is responsible for rigorously reviewing data and information regarding drugs to ensure their safety and efficacy, as well as the truthfulness and adequacy of their labeling, before they are permitted to enter the market.[9] The agency also has extensive authority over drug products introduced into distribution in the U.S., including with regard to how drugs are manufactured and distributed. The U.S. drug supply chain is increasingly global, and the FDA's responsibility for addressing the growing complexities and threats,

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[8] *See* 21 U.S.C. § 393(a)-(b)

[9] *See id.* §§ 355, 393(b).

such as diversion, counterfeit drugs, and importation of unapproved or otherwise substandard drugs has never been more important.[10]

To that end, Congress amended the FDCA by enacting the Drug Supply Chain Security Act (DSCSA), Pub. L. No. 113-54, tit. II, 127 Stat. 599 (2013), a few years ago to more tightly regulate the supply chain and thereby address unsafe, ineffective, and counterfeit drugs. The DSCSA establishes a federal system for tracing prescription drug products through the pharmaceutical supply chain and requires trading partners to provide, receive, and maintain certain product and distribution information.[11]

The law requires full supply chain traceability—from the drug manufacturer all the way through to the entity that dispenses the drug to a patient. By doing so, the law strengthens the integrity of the U.S. drug supply chain and reduces the likelihood of counterfeit or unapproved drugs being distributed in the U.S.

As stated by FDA Commissioner Scott Gottlieb, M.D., at a February 2018 public meeting on enhanced drug distribution security:

> Patient safety is at the core of FDA's public health mission; and ensuring reliable patient

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[10] *Drug Supply Chain Integrity*, FDA, https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm (last updated June 13, 2017).

[11] *See* 21 U.S.C. § 360eee-3(b). The DSCSA identifies and defines the types of entities in the drug supply chain, *i.e.*, manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers. *Id.* § 360eee.

> access to safe and effective medicines requires maintaining a closed, secure U.S. drug supply chain for the distribution and delivery of finished drug products.
>
> Every link in that chain must be secure: From the moment finished drug products leave manufacturing facilities to final delivery to pharmacies or providers' offices where medicines are ultimately dispensed to patients.[12]

The CSA and its implementing regulations is an additional layer of federal law applicable to the regulation of controlled substances. The CSA's focus, in relevant part, is on preventing these substances from being diverted for illegal purposes.[13] The CSA is important here, because numerous drugs that have been used or considered for use in lethal injections are controlled substances under the CSA, including Sodium Thiopental, Midazolam, Fentanyl, Hydromorphone, Pentobarbital, Amobarbital, Secobarbital, and Diazepam.[14]

The CSA generally requires anyone who handles controlled substances to register with the U.S. Drug Enforcement Administration (DEA).[15] Registrants

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[12] Scott Gottlieb, M.D., Comm'r, FDA, Remarks at the FDA Public Meeting on Enhanced Drug Distribution Security under the Drug Supply Chain Security Act (DSCSA) (Feb. 28, 2018), *available at* https://www.fda.gov/NewsEvents/Speeches/ucm598719.htm.

[13] Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16236, 16237 (Mar. 31, 2010); *see* 21 C.F.R. §§ 1300–1399.

[14] 21 U.S.C. § 812; 21 C.F.R. § 1308.11–15.

[15] 21 U.S.C. §§ 878(a), 880.

are required, among other things, to "provide effective controls and procedures to guard against theft and diversion of controlled substances."[16]

By establishing a "closed" drug distribution system, the FDA and DEA oversee the federal system to protect the public from the risks posed by potentially unsafe or ineffective drugs obtained from unverified sources and from drugs of abuse.[17]

Permitting drugs to be imported, compounded, and distributed in ways that effectively shield them from the scrutiny mandated in the governing federal-law framework presents an increased risk of products that are impure and unsafe. Even worse, there is no guarantee that drugs obtained by circumventing the federal system of verification and control are even the drugs they purport to be.

Once an illicit supply channel is established with a supplier, it is extremely challenging to control which drug products move through it, and which customers they reach, particularly in a context where the FDA, DEA and state boards of pharmacy are prevented from performing their usual regulatory duties because of secrecy.[18]

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[16] 21 C.F.R. § 1301.71(a).

[17] Letter from William K. Hubbard, Assoc. Comm'r for Policy & Planning, FDA, to Gregory Gonot, Deputy Attorney Gen., State of California, (Aug. 25, 2003), *available at* https://web.archive.org/web/20170603210131/http://fda.gov/drugs/drugsafety/ucm179893.htm ("Hubbard Letter").

[18] Prashant Yadav et al., *When Government Agencies Turn to Unregulated Drug Sources—Implications For the Drug Supply Chain & Public Health Are Grave*, J. Am. Pharmacists Ass'n

States and their departments of correction are not exempt from the mandatory responsibilities and restrictions set forth in the FDCA and CSA and their implementing regulations. Actions to circumvent or undermine the federal system by obtaining drugs outside of the closed system through alternative and illegal pathways are violations of the FDCA and CSA and expose the public to risk.

II. STATES ARE CIRCUMVENTING THE EXTENSIVE FEDERAL PHARMACEUTICAL REGULATORY SYSTEM THAT PROTECTS PUBLIC HEALTH.

In their efforts to obtain drugs to carry out lethal injections States have blatantly acted outside the bounds of the governing federal regulatory system. They have also sought to undermine contractual controls that companies have put in place to protect drugs from being diverted and misused.[19] And in so doing, they have ignored repeated warnings from companies that buying drugs outside of the authorized distribution channels creates dangers for public health and puts patients at risk:

> [T]he use of the medicines for lethal injections creates a public-health risk by undermining the safety and supply of lifesaving medicines. Improperly procured medicines from unauthorized sellers are at risk of adulteration or chemical change * * * [and could]

(forthcoming 2018), *available at* https://www.japha.org/article/S1544-3191(18)30336-4/pdf.

[19] Eckholm, *supra* note 6.

> place patients * * * across the country at risk."[20]

The lengths to which State boards of correction have gone to acquire drugs for lethal injection is well illustrated by the allegations made by Alvogen in recently filed litigation.[21] Alvogen's complaint alleges, *inter alia*, misrepresentation, fraud, deception, subterfuge, and false pretenses by the Nevada Department of Corrections in acquiring a supply of Alvogen's Midazolam.

States' actions have serious consequences for consumers and patients, who face an enhanced risk of illegal and substandard drugs being diverted into the otherwise legitimate distribution system.

A. States Have Violated The FDCA By Importing Unapproved Drugs For Use In Executions.

As noted, the FDCA creates a " 'closed' drug distribution system, which helps ensure that the domestic drug supply is safe and effective."[22] It contains a rigorous drug approval process that is intended to ensure that drugs distributed in the United States

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[20] Motion for Leave to File Amicus Brief, Ex. C at 4 (Amicus Brief of Fresenius Kabi USA, LLC & West-Ward Pharms. Corp.), *State* v. *McKesson Medical-Surgical Inc.*, No. CV-17-317 (Ark. Apr. 20, 2017).

[21] *See generally* Complaint For Emergency Injunctive Relief & Return of Illegally Obtained Property, *Alvogen Inc.* v. *Nevada State Dep't of Corr.*, No. A-18-777312-B (Nev. Clark Cty. Dist. Ct. July 10, 2018) ("*Alvogen* Compl.").

[22] Hubbard Letter, *supra* note 17.

are safe and effective.[23] As the FDA itself has explained, the FDA has "long taken the position that consumers are exposed to a number of risks when they purchase drugs from foreign sources" that are not inspected by the FDA and approved to manufacture products for importation, because those sources may, *inter alia*, "dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use."[24]

Notwithstanding the FDCA's clear prohibition on importing of unapproved drugs from foreign sources, States have done just that to obtain drugs for lethal injections. And this has not been a one-time occurrence, but a repeated scenario. The result is that States are undermining the closed drug distribution system and exposing patients and the wider American public to harm.

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[23] *The FDA's Drug Review Process: Ensuring Drugs Are Safe & Effective*, FDA, https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last updated Nov. 24, 2017).

[24] *Canadian Prescription Drug Importation: Is There a Safety Issue?: Hearing Before the Subcomm. on Human Rights and Wellness of the H. Comm. on Government Reform*, 108th Cong. 24 (2003) (statement of William K. Hubbard, Associate Commissioner for Policy & Planning, FDA); *see Unapproved Prescription Drugs: Drugs Marketed in the United States That Do Not Have Required FDA Approval*, FDA, *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/default.htm ("The Agency has serious concerns that drugs marketed without required FDA approval may not meet modern standards for safety, effectiveness, quality, and labeling.").

In 2010, for example, ten states acquired supplies of Sodium Thiopental ("Thiopental") from Dream Pharma, a pharmacy in England apparently operating out of a back room in a driving school.[25] The drug product was not FDA-approved and its importation was illegal. But the states acted covertly, outside of the protections provided by a closed system supply chain, and the products entered the United States despite their unapproved status.

Although an execution typically requires just 2-5 grams of Thiopental, Dream Pharma shipped over one kilogram to the United States.[26] Given the large quantities imported (these quantities were enough for 200 to 500 executions) and the price at which the drug was sold (in some instances more than 35 times the market price for the drug at the time), it appears that Dream Pharma was shipping more Thiopental than required for use in lethal injection.[27] And that

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[25] Schwartz, *supra* note 7; Jim Edwards, *Drug Company? Driving School? It's All the Same in the Lethal Injection Business*, CBS NEWS: MONEYWATCH (Jan. 6, 2011, 6:09 PM), https://www.cbsnews.com/news/drug-company-driving-school-its-all-the-same-in-the-lethal-injection-business/.

[26] *See* ACLU of Northern California, *Timeline for California's "Secret Mission" for Lethal Injection Drugs* (Aug. 11, 2011), https://www.aclunc.org/blog/timeline-california%E2%80%99s-secret-mission-lethal-injection-drugs; Carol Williams, *California Now Has Enough Drugs to Execute 175 Death Row Inmates*, L.A. TIMES (Dec. 7, 2010, 12:38 PM), http://latimesblogs.latimes.com/lanow/2010/12/drugs-for-state-executions-came-from-arizona-and-britian-prison-officials-say.html.

[27] *See* Management Sciences for Health, International Drug Price Indicator Guide A-114 to A-115 (Julie E. Frye, ed. 2009), http://mshpriceguide.org/wp-content/uploads/2016/06/

is exactly what happened. Quantities of the unapproved Thiopental were sold to at least one pharmacy servicing the general public and "substantial quantities" of the medicine went "missing" from San Quentin prison in California. It turned out that the person responsible for maintaining custody of the drug at that California prison was an illicit drug smuggler.[28]

State departments of corrections have also sought to purchase unapproved Thiopental from suppliers in India. In one instance, a company was forced to issue a product recall because the company could not guarantee the drugs' safety because the drugs had been "illegally diverted from the company's supply chain" and were potentially "unsafe."[29] Another potential source was a small drug supplier operating out of a mall in India, which was shut down shortly thereafter for illegal online sales of psychotropic

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MSH-International-Drug-Price-Indicator-Guide-2009.pdf; Andrew Welsh-Huggins, *FDA Has Helped Two States Obtain Anesthetic Used in Executions*, WASH. POST (Jan. 12, 2011, 8:09 PM), http://www.washingtonpost.com/wp-dyn/content/article/2011/01/12/AR2011011205616.html.

[28] *Beaty*, 853 F. Supp. 2d at 34-35, 42 n.8.

[29] Chris McDaniel & Tasneem Nashrulla, *Texas Almost Bought Execution Drugs From 5 Men In India Who Were Accused Of Selling Illegal Party Pills*, BUZZFEED NEWS (Jan. 26, 2017 6:09 PM), https://www.buzzfeed.com/chrismcdaniel/texas-almost-bought-execution-drugs-from-5-guys-overseas-who?utm_term=.nherx7aD#.xxRMq8PD; *Company Recalls Nebraska Lethal Injection Drug*, KEARNEYHUB (May 10, 2012), https://www.kearneyhub.com/news/local/company-recalls-nebraska-lethal-injection-drug/article_f5635256-9a9e-11e1-9a66-0019bb2963f4.html.

drugs and opioids to consumers in the United States.[30]

These situations highlight the broader problem: once a State or other entity finds an illicit supply channel, controlling that supply channel and tracking where the products are used is extremely difficult—if not impossible.[31]

B. States Have Obtained Compounded Drugs Of Questionable Quality From Unlicensed And Secret Pharmacies.

States' increasing reliance on compounding pharmacies is exacerbating the public health risks. Compounded lethal injection products may be made from illegally imported bulk drug substance and are not reviewed by the FDA for safety, effectiveness, or quality.[32] The FDA has on numerous occasions expressed concern about the risks of poor compounding practices, including product contamination, lack of sterility, and product that is sub- or super-potent.

Monitoring and oversight of pharmacy compounding is limited in many states.[33] And in a context in which drug secrecy laws (discussed more below) put such activities outside the view of state and federal

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[30] McDaniel & Nashrulla, *supra* note 29.

[31] Yadav et al., *supra* note 18.

[32] *Compounding & the FDA: Questions & Answers*, FDA, https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm339764.htm.

[33] *Id.*

regulators alike, the risks are amplified. The resulting "regulatory vacuum" endangers public health.[34]

History has born this out already. In 2012, a drug safety crisis arose from products compounded at the New England Compounding Center (NECC). Notably, NECC operated in the open—unlike pharmacies that compound lethal injection products behind the cloak of state secrecy laws. And even so, more than 750 people in 20 states developed fungal infections from injectable products compounded at NECC, and more than 60 people died.[35] Compounding pharmacies selected by states to make execution drugs have repeatedly been found to be in violation of both state and federal regulations governing the safe compounding and distribution of medicines, including controlled substances. Shielded from scrutiny of federal agencies and exempted from proper regulation by state regulators, these pharmacies have in some instances continued to provide drugs for American consumers for many months before the dangers their poor practices created for public health came to light.

For example, an Oklahoma compounding pharmacy called The Apothecary Shoppe is thought to have provided or offered compounded medicines for executions in three States, despite not being licensed to dispense or distribute controlled substances in any of them.[36] After its activities became known, the FDA

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[34] Yadav et al., *supra* note 18.

[35] *Compounding & the FDA: Questions & Answers*, FDA, *supra* note 32.

[36] Ed Pilkington, *Tulsa Pharmacy Faces Questions Over Lethal Drug to be Used in Execution*, THE GUARDIAN (Jan. 28,

and the Oklahoma Board of Pharmacy conducted an investigation that ultimately uncovered a whopping 1,892 violations and led to enforcement action on the licenses of the pharmacy and head pharmacist.[37]

These risks are increased when States seek to have drugs compounded that are not commercially available, such as Pentobarbital, a Schedule II controlled substance and known drug of abuse.[38] Pentobarbital is listed in twenty-one States' execution protocols,[39] and a number of States have sought to use compounded Pentobarbital in executions. Pharmacists have noted that the active ingredient for Pentobarbital is not available domestically and warned that anyone compounding Pentobarbital for executions is likely doing so "using ingredients procured on the black market."[40] To reiterate the obvious, illicit

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2014, 5:53 PM), https://www.theguardian.com/world/2014/jan/28/tulsa-compounding-pharmacy-lethal-injection-execution.

[37] Chris McDaniel, *Pharmacy That Mixed Executions [sic] Drugs Is Being Sold After Admitting Numerous Violations*, BuzzFeed News (Apr. 21, 2016, 10:45 PM), https://www.buzzfeed.com/chrismcdaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc?utm_term=.kcopbMDX4#.ycDLE46a1.

[38] *See* Yadav et al., *supra* note 18; Letter from Dr. Philip D. Hansten et al. to Timothy Lockwood, Chief, Regulation & Policy Mgmt. Branch, Cal. Dep't of Corr. & Rehab. (Aug. 14, 2017), *available at* http://lethalinjectioninfo.org/wp-content/uploads/2018/06/2017_08_13_PUB-Comment-on-California27s-Lethal-Injection-Protocol-Amendme....pdf.

[39] *Current State-By-State Execution Protocols*, Lethal Injection Info. Ctr., http://lethalinjectioninfo.org/lethal-injection-protocols/ (last visited July 23, 2018).

[40] Hansten et al., *supra* note 38, at 1.

supply channels involve risks that drug products may be substandard, counterfeit or contaminated.

By seeking drugs through unauthorized channels and tasking lightly regulated compounding pharmacies with compounding drugs that are not commercially available, States are putting the general public at risk of receiving unsafe drugs that make their way into the public stream of commerce.

C. States Have Breached Supply Chain Controls And Misled Healthcare Providers In Efforts To Obtain Drugs For Lethal Injection

Federal law requires manufacturers and distributors of controlled substances to perform specific activities to ensure the safety, integrity, and security of the U.S. pharmaceutical supply chain and to protect the public from harm. One of those requirements is to have a mechanism for detecting suspicious orders of controlled substances—which when they occur, must be reported to the DEA.[41] Another is to build systems to identify and trace certain prescription drugs as they are distributed in the United States.[42] These requirements, and many others like them, are intended to enhance the FDA's ability to protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. They also seek to improve detection and removal of potentially dangerous drugs from the

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[41] 21 U.S.C. § 828; 21 C.F.R. § 1301.74; *id.* pt. 1305.

[42] *See* Drug Supply Chain Security Act, Pub. L. No. 113-54, tit. II, 127 Stat. 599.

pharmaceutical supply chain to protect public health across the country.

Manufacturers and distributors of controlled substances can effectively perform these activities only with visibility over their supply chains from start to finish. But States, endeavoring to procure execution drugs that are restricted for sale for this purpose, have resorted to secrecy and surreptitious means to divert drugs outside of authorized supply channels. One company characterized these actions as "subterfuge."[43]

Three examples provide a flavor of how this plays out. In Ohio, officials wanted to purchase Pentobarbital, a Schedule II controlled substance, for use in executions. Because the manufacturer had prohibited any sale of the drug to prisons for such use, state officials used the Ohio Department of Mental Health as the purchaser.[44] A state official went so far as to advise his colleague in the Ohio Department of Mental Health:

> When you call them to see if they will sell to us make sure you say we are the Department of Mental Health do not mention anything about corrections in the phone call or what we use the drug for.[45]

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[43] *Alvogen* Compl., *supra* note 21, ¶¶ 5-123; Response to Emergency Petition for Immediate Writ of Mandamus at 21, *State* v. *McKesson Medical-Surgical Inc.*, No. CV-17-317 (Ark. Apr. 20, 2017).

[44] *See* David Jolly, *Danish Company Blocks Sale of Drug for U.S. Executions*, N.Y. TIMES (July 1, 2011), https://www.nytimes.com/2011/07/02/world/europe/02execute.html.

[45] Caplan, *supra* note 7.

In Texas, officials used the DEA certificate of registration of a defunct hospital to procure execution drugs and wrote a false prescription for the drug made in the name of the warden.[46] They were later accused of misleading sellers about the purpose for which they were ordering execution drugs.[47]

And in Louisiana, the Department of Corrections ordered Hydromorphone, a Schedule II controlled substance, for use in an execution, but led the supplying hospital to believe the drug was being ordered for a patient. The hospital would not have filled the order had it known the true purpose.[48]

Companies have repeatedly warned of the risks this kind of behavior poses to public health. For example, last year, pharmaceutical distributor McKesson sued the State of Arkansas and Arkansas Department of Corrections for using "false pretense, trickery, and bad faith" in purchasing Vecuronium Bromide for use in executions.[49] McKesson alleged, among other

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[46] Letter from Maurie Levin, Adjunct Professor, Univ. of Texas Sch. of Law, & Sandra Babcock, Clinical Professor, Nw. Univ. Sch. of Law, to Hon. Eric H. Holder, Jr., Attorney Gen., U.S. Dep't of Justice (Mar. 30, 2011), *available at* http://standdown.typepad.com/LI-Foster-LtrToHonEricHolder.pdf.

[47] Eric Nicholson, *Texas, Fresh Out of Pentobarbital, Begins Experimenting With Execution Drugs* (Oct. 2, 2013, 3:40 PM), http://www.dallasobserver.com/news/texas-fresh-out-of-pentobarbital-begins-experimenting-with-execution-drugs-7125883.

[48] Della Hasselle, *In Rush to Find Lethal Injection Drug, Prison Officials Turned to a Hospital*, THE LENS (Aug. 6, 2014, 5:17 PM), https://thelensnola.org/2014/08/06/lake-charles-memorial-hospital-sold-execution-drug-to-state/.

[49] Response to Emergency Petition for Immediate Writ of Mandamus, *supra* note 43, at 21; *see also* Alan Blinder, *Arkan-*

things, that the Department of Corrections purchased the products under the medical license of an Arkansas physician and had the products shipped to a healthcare facility, misrepresenting "that the order was placed at the request of or for the benefit of the physician and would be used for legitimate medical purpose."[50]

Two other companies whose drugs Arkansas had obtained for use in executions submitted a brief in support of McKesson, stating that "[t]he use of their medicines for lethal injections violates contractual supply-chain controls that the Manufacturers have implemented."[51] The companies warned of grave public health risks associated with the use of these medicines in executions:

> [T]he use of the medicines for lethal injections creates a public-health risk by undermining the safety and supply of lifesaving medicines. Improperly procured medicines from unauthorized sellers are at risk of adulteration or chemical change * * * [and could] place patients * * * across the country at risk.[52]

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sas Judge Moves to Block Executions, N.Y. TIMES (Apr. 14, 2017), https://www.nytimes.com/2017/04/14/us/arkansas-is-accused-of-deception-in-buying-drug-used-in-executions.html.

[50] Verified Complaint for Emergency Injunctive Relief & Return of Illegally Obtained Products ¶ 13, *McKesson Medical-Surgical Inc.* v. *State*, No. 60CV-17-1921 (Ark. Pulaski Cty. Cir. Ct. Apr. 14, 2017); *see also id.* ¶¶ 34, 56.

[51] Amicus Brief of Fresenius Kabi USA, LLC & West-Ward Pharms. Corp., *supra* note 20, at 1.

[52] *Id.* at 4.

The Court's opinion should make clear that nothing in *Glossip* condones such dangerous behavior.

D. States' Secrecy Laws Hide Potentially Illegal And Unsafe Conduct From Scrutiny.

An increasing number of States[53] have implemented laws or policies commonly referred to as "secrecy laws" that shield their execution drug procurement practices from public view and from scrutiny by regulatory authorities.[54]

Generally, these laws allow state officials to refuse to disclose information about the nature and source of drugs used in executions. This undermines companies' abilities to assure the integrity of their supply chains and the safety and efficacy of drugs, as well as the ability of agencies tasked with regulating the safety and effectiveness of drug products and of the supply chain.

Under the typical terms of many of these laws, pharmacies and other "suppliers" providing medicines for use in executions are defined as "members of the execution team" and their identities are hidden from the public and state and federal regulators. In some states, anyone who discloses the identity or identifying information about a supplier of execution

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[53] Currently, 19 states have enacted such laws: Alabama, Arizona, Arkansas, Florida, Georgia, Idaho, Indiana, Mississippi, Missouri, Nebraska, North Carolina, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, Texas, Virginia, and Wyoming.

[54] *See* LETHAL INJECTION INFO. CTR., RESPECTING CORPORATE CONTRACTS: STATE-BY-STATE RISK INDEX (July 2018), *available at* http://lethalinjectioninfo.org/wp-content/uploads/2018/06/State-by-State-Risk-Index.pdf.

drugs may be subject to civil or criminal penalties.[55]

In a number of states, the "prescription, preparation, compounding, dispensing, and administration of a lethal injection" is defined as no longer being within the practice of medicine, nursing, or pharmacy, and those who engage in those acts are explicitly exempted from regulation by the state boards of pharmacy and medicine.[56]

In Missouri, for example, the "execution team" includes "individuals who prescribe, compound, prepare or otherwise supply the chemicals for use in the lethal injection procedure," all of whom are shielded from public or regulatory scrutiny.[57] In addition, if a member of the execution team is licensed by a board or department, the licensing authority is prohibited from taking disciplinary action against the licensee for actions related to the execution drug.[58] Further, one who discloses the identity or a record which identifies a person as

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[55] DEATH PENALTY INFO. CTR., *supra* note 4.

[56] *See e.g.*, Ala. Code § 15-18-82.1(f); Fla. Stat. § 922.105(6); Ga. Code Ann. § 17-10-38(c); Ind. Code § 35-38-6-1(1)(e); Idaho Code § 19-2716A; Neb. Rev. Stat. § 83-966(2); N.H. Rev. Stat. Ann. § 630:5(XVI); N.C. Gen. Stat. § 90-1.1; Or. Rev. Stat. Ann. § 137.473(2); Va. Code Ann. § 53.1-234; Wyo. Stat. Ann. § 7-13-904(a).

[57] DEATH PENALTY INFO. CTR., *supra* note 4 (internal quotation marks omitted).

[58] *See id.*

being a current or former member of an execution team is liable for actual and punitive damages.[59]

Without the Missouri secrecy law, the thousands of regulatory violations by the Apothecary Shoppe, which supplied lethal injection drugs to the Missouri Department of Corrections, likely would have been uncovered years earlier.

In Oklahoma, officials acknowledged the damaging role that secrecy played in their state when announcing their decision to change execution methods from lethal injection to nitrogen hypoxia:

> One of the things that jumped out at me at the Grand Jury report * * *, was the lack of total transparency. * * * For the better part of two years and about 45 days, my discussions with individuals, seedy individuals who had access to drugs, even other states that have access to drugs, has all proven for naught. What came out of that conversation for me * * * was *there was no way to assure chain of custody, which leads to a lot of problems.*[60]

When a state department of corrections promotes opacity in the supply chain, these actions create future risks and undermine drug safety.[61]

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[59] *See id.*

[60] Joe Allbaugh, Dir., Oklahoma Dep't of Corr., Press Conference Regarding Oklahoma's Abandonment of Lethal Injection at 0:30/2:30 (Mar. 15, 2018), *available at* http://lethalinjectioninfo.org/oklahoma-abandons-lethal-injection/ (emphasis added).

[61] Yadav et al., *supra* note 18.

An erroneous reading of *Glossip* that would have lethal injection as the only method of execution available to states encourages state officials to seek drugs through means that create dangers to patients and the public.

E. States Are Expanding The List Of Drug Products Used In Lethal Injections, Creating Increased Risks.

As drugs used in the traditional three-drug execution protocol have become unavailable, States have added new drugs to their execution protocols. Twenty-one different drugs have now been used or proposed for use in lethal injections.[62] These include highly potent or addictive drugs of abuse, such as: Fentanyl, Hydromorphone, Pentobarbital, Amobarbital, Secobarbital, and Diazepam.

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[62] *See, e.g.*, Press Release, Nevada Dep't of Corr. (Aug. 17, 2017), http://doc.nv.gov/uploadedFiles/docnvgov/content/About/Press_Release/press%20release%20exec%20drugs.pdf (Nevada Department of Corrections proposed using diazepam, fentanyl, and cisatracurium besylate in a three-drug protocol); *Current State-By-State Execution Protocols*, Lethal Injection Info. Ctr., *supra* note 39 (Louisiana authorizes the use of Midazolam and Hydromorphone in a two-drug protocol; Texas authorizes the use of pentobarbital in a one-drug protocol); Monte Morin, *Proposed Lethal Injection Drugs Once Hailed as 'Sleep Cures'*, L.A. Times (Nov. 7, 2015, 10:10 AM), http://www.latimes.com/science/sciencenow/la-sci-sn-lethal-injection-20151106-story.html (California Department of Corrections and Rehabilitation proposed the use of amobarbital and secobarbital for use in executions).

Fentanyl and Hydromorphone have been at the center of the opioid crisis,[63] and many of the other drugs listed in state execution protocols are Schedule II Controlled Substances, meaning that they have a "high potential for abuse."[64]

Because of their abuse potential, all of these products are subject to strict distribution controls to prevent diversion and misuse. And because the manufacturers have contractually prohibited these products' use in executions, adding these drugs to lethal injection protocols leads to procurement outside of legitimate supply channels and the protections imposed by the CSA. Creating an alternative supply stream for these dangerous drugs of abuse—essentially a state-sponsored black market—increases the already overwhelming public health risk.[65]

In addition, many of the drugs that are used or have been proposed for use in executions are considered to be essential medicines for patient care. These include Fentanyl, Propofol, Midazolam, Phenobarbital, Diazepam, Potassium Chloride, Vecuronium Bromide, and Hydromorphone.[66] As a num-

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[63] *See* Opioid Overdose Crisis, Nat'l Inst. on Drug Abuse, Nat'l Insts. of Health, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last updated Mar. 2018).

[64] Drug Enforcement Admin., U.S. Dep't of Justice, Drugs of Abuse 9 (2017 ed.), https://www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.

[65] Yadav et al., *supra* note 18.

[66] *See* World Health Org., *supra* note 5; World Health Org., WHO Model List of Essential Medicines (20th ed. amended Aug. 2017), http://www.who.int/medicines/publications/essential

ber of companies have warned, including these drugs in execution protocols could lead to shortages of the drugs for legitimate medical use.[67]

III. WHEN STATES CIRCUMVENT THE DRUG SAFETY REGIME, THEY CREATE SERIOUS RISKS.

The FDCA and CSA form the basis for an extensive and integrated system of drug regulation—including a closed drug distribution system—that protects the public health. Within that system, pharmaceutical manufacturers have understandably and legally

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medicines/20th_EML2017_FINAL_amendedAug2017.pdf?ua=1. The World Health Organization (WHO) updates and publishes a Model List of Essential Medicines every two years to reflect the global standard for medicines that are necessary to meet the priority health care needs of a population. In a functioning health system, essential medicines of an assured quality should be available at all times in an adequate amount. *See Essential Medicines & Health Products*, World Health Org., http://www.who.int/medicines/services/essmedicines_def/en/ (last visited July 23, 2018).

[67] Amicus Brief of Fresenius Kabi USA, LLC & West-Ward Pharms. Corp., *supra* note 20, at 4-5. A number of the drugs used in executions are already officially in short supply. *See FDA Drug Shortages: Current & Resolved Drug Shortages & Discontinuations Reported to FDA*, FDA https://www.accessdata.fda.gov/scripts/drugshortages/ (last visited July 23, 2018). In addition, a recent investigation overseen at Emory University hospital found that four states have been stockpiling drugs in short supply for use in executions, in quantities that would be sufficient to treat 11,257 patients in life-saving surgeries. *See* Ed Pilkington, *States are Stockpiling Lethal Injection Drugs That Could Be Used to Save Lives*, The Guardian (Apr. 20, 2017, 11:23 AM), https://www.theguardian.com/world/2017/apr/20/states-stockpiling-lethal-injection-drugs-arkansas-execution.

taken steps to prevent the use of their drugs for lethal injection.

As discussed above, this in turn has led states to operate outside of the federal drug regulatory system to obtain drugs for use in prisoner executions. These increasingly desperate moves have led to a spiraling of risks to patients receiving products that may be contaminated, counterfeit, adulterated, sub- or super-potent, or perhaps not even what their labelling says they are.

Illicit supply channels create an undeniable risk that is broader than lethal injection. State secrecy laws take a daunting task—ensuring the safety of the nation's drug supply—and make it ever more difficult for federal and state regulators to meet their responsibilities.[68] Secrecy laws exacerbate the risks, preventing the FDA and DEA from conducting effective investigations into illegal activity that would enable steps to be taken to mitigate the risk of substandard drugs being used on patients or drugs of abuse reaching the general public.

States are increasingly turning to pharmacy compounded drugs, where the risks are particularly acute, and are exacerbated by an absence of scrutiny, due to execution secrecy laws. The FDA has recognized the importance of strong state oversight of compounding in preventing another tragedy like the

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[68] *See* Yadav et al., *supra* note 18, at 2, 4; *see also* INST. OF MED. OF NAT'L ACADEMIES, COUNTERING THE PROBLEM OF FALSIFIED & SUBSTANDARD DRUGS (Gillian J. Buckley & Lawrence O. Gostin eds., 2013).

NECC fungal meningitis outbreak.[69] State secrecy laws make it increasingly likely that such oversight will not occur. The growing interest in drugs with a high risk of abuse for lethal injections also presents an enhanced cause for concern. There is no purpose that justifies the creation of a state-sponsored black market for such products.

The paths states have created for obtaining drugs for lethal injection increase the likelihood of patients being harmed by illegal, substandard drugs or the unavailability of legitimate drugs, and the public facing yet another source of drugs of abuse. They also undermine pharmaceutical manufacturers' ability to appropriately protect their businesses by restricting the purposes for which their drugs are distributed.

None of these consequences, let alone the accumulation of them, is justified by States' desires to carry out prisoner executions by lethal injection. The Court should make clear that any actions to carry out execution by lethal injection is subject to, and must be consistent with, the extensive federal regulatory scheme that protects the integrity of the nation's drug supply, the safety and effectiveness of drug products, and the public health.

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[69] *Compounding & the FDA: Questions & Answers*, FDA, *supra* note 32.

CONCLUSION

For the reasons stated above, *amici curiae* respectfully urge the Court to hold that the pursuit of execution by lethal injection does not permit a state to violate federal laws and regulations that protect the public health.

Respectfully submitted,

JESSICA L. ELLSWORTH*
Counsel of Record
PHILIP KATZ
LYNN W. MEHLER
LOWELL M. ZETA
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5886
jessica.ellsworth@hoganlovells.com

Counsel for Amici Curiae

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APPENDIX

APPENDIX
LIST AND AFFILIATIONS OF *AMICI CURIAE*[1]

ANTHONY ABSALOM
Professor of Anesthesiology
University Medical Center Groningen,
Groningen University, The Netherlands

DONALD F. DOWNING
Clinical Professor
University of Washington School of Pharmacy

MARK A. EDGAR, M.D.
Associate Professor of Pathology
Emory University School of Medicine

DR. LEONARD L. EDLOE, PHARMD
Former President of the American Pharmacists
Association Foundation

WILLIAM E. FASSETT, PHD, RPH, FAPHA
Professor Emeritus of Pharmacy Law & Ethics
College of Pharmacy and Pharmaceutical Sciences
Washington State University—Spokane
Past President
Academy of Pharmaceutical Research and Science
American Pharmacists Association

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[1] *Amici* appear in their individual capacities; institutional affiliations are listed here for identification purposes only.

LAWRENCE O. GOSTIN
University Professor
Founding Linda D. & Timothy J. O'Neill Professor of Global Health Law
Faculty Director, O'Neill Institute for National & Global Health Law
Director, World Health Organization Collaborating Center on Public Health Law & Human Rights
Georgetown University Law Center
Georgetown University

MARGARET A. HAMBURG M.D.
Former Commissioner
U.S. Food and Drug Administration

PHILIP D. HANSTEN
Professor Emeritus
University of Washington

JOHN B. HERTIG, PHARMD, MS, CPPS
Associate Director
Center for Medication Safety Advancement
Purdue University College of Pharmacy

LEONIDAS GEORGE KONIARIS, M.D.

ROBERT B. GREIFINGER, M.D.
Consultant, Correctional Health Care

JAMES RUBLE, PHARMD, JD
Associate Professor,
Department of Pharmacotherapy
Adjunct Associate Professor, Medical Ethics and Humanities, Department of Internal Medicine

University of Utah College of Pharmacy and School of Medicine

JOSHUA M. SHARFSTEIN, M.D.
Former Principal Deputy Commissioner
U.S. Food and Drug Administration

J. ROBERT SNEYD
Dean and Professor of Anesthesia
Faculty of Medicine and Dentistry
University of Plymouth

REBECCA L. WEINTRAUB, M.D.
Assistant Professor
Harvard Medical School
Associate Physician
Brigham and Women's Hospital

TIMOTHY M. WESTMORELAND, B.A., J.D.
Professor from Practice
Senior Scholar, O'Neill Institute for National and Global Health Law
Georgetown University Law Center
Georgetown University

PRASHANT YADAV, PH.D.
Visiting Scholar
Harvard Medical School

PATRICIA J. ZETTLER
Associate Professor
Georgia State University College of Law
Former Associate Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration